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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,693	08/09/2001	Robert Booker	PA-5265-RFB	4288

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 03/01/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,693

Applicant(s)

BOOKER ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 20-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 and 20-23 is/are allowed.
- 6) ☒ Claim(s) 1-15 and 24-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Parenthesized numerals pertain to the particular claim(s) being addressed.)

Claims 1, 3, 7-9, 11, 26, 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Drost et al (US6036645). Drost et al teaches structure and method of use of a transducer head 24 which includes an ultrasound bloodflow sensing transducer col. 1 lines 6-8 and col. 3 lines 13-18), its connecting cable wires (col. 3 line 7) , a shapable portion 16 which is sized and dimensioned to be hooked around small vessels intra-operatively during surgery, the portion 16 being malleable by the use of a stainless steel guidewire which is also stiff enough that it retains the operator-contoured shape while in use. Since the brain contains ordinary blood vessels of smaller caliper the limitation 'sized and dimensioned for introduction....brain' is effectively a description of a small-vessel device in the usage context of brain surgery application, whereupon col. 1 lines 57-64 of Drost et al teaching a small-vessel probe is anticipatory considered together with col. 2 line 65 – line 18 as aforementioned. In the alternative, it would have been inherently obvious to use the probe of Drost et al in brain neurosurgery since preservation of normal blood perfusion is often at the center of the procedures in this field. (Claims 1, 9, 26). A malleable wire would inherently function to provide malleability at its neck particularly where the sensor head is stated to move in all directions (col. 3 lines 15-18). (Claims 3, 32). When 16 is co-axial with 22, the transducer emission face is oriented

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perpendicular (Claim 7). The ninety degree swivel shown allows the transducer emission surface to be parallel to axis 22. (claim 8). The stainless steel wire may be construed as a 'core wire' since a wire being solid it would be impossible for the cable wires to be located other than 'thereabout' as called for by the claim. (Claim 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al as applied to claims 1, 7 above, and further in view of Gade (US4945896). It would have been obvious in view of Gade Fig. 1 and col. 2 lines 46-52 and col. 5 top to use a bloodflow sensor in neurosurgical brain procedures since instrument pressure on the brain can result in additional hypoxic damage from underperfusion. (claims 1, 27-28). It would also have been obvious to at least partly house or reside the flow sensor within the malleable probe portion i.e. blade 18 of Gade since this results in a smooth instrument contour for presentation against the tissue interface for which flow monitoring is desired. (Claim 4).

Claim 2, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al. Drost et al is applied as against apparatus and method claims 1 and 26 supra. An artisan working with steel would be expected to know that since most

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torsional strength in a rod resides in the outer cylinder, the substitution of steel tubing for steel wire to effect shape retaining bendability would be inherently obvious since the result would be lighter but only slightly more malleable than the solid case.

Claims 4-6, 29-30, 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al as applied to claims 1, 26 above, and further in view of Yock et al.

It would have been obvious in view of Yock et al to house a Doppler transducer 34 within a probe portion during an invasive surgical procedure since in the case of metal stylet devices this provides structural protection and metal shielding to the measurement where a case ground if used prevents shock as well. (Claim 4).

Encasement within epoxy 46 serves to mechanically fix the transducer as well as allow tailoring of backing impedance. (claims 5-6, 29-30, 33-37, 40). The claim 7-8 discussion re Drost et al supra carries forward. (claims 38-39). The

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al as applied to claim 9 above, and further in view of Salmon et al (US5503155, of record). It would have been obvious in view of Salmon et al col. 1 lines 42-64 that the cable wires called for in Drost et al would be malleable since traditional Doppler wire conductors behave in this fashion. (Claim 10). Since Salmon et al notes that these wires are usually twisted to cling to the support shaft they are characterizable as helical. Drost et al otherwise teaches use of an outer covering for additional structural support, see col. 2 lines 53-63. (claims 11-12).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al as applied to claim 1 above, and further in view of Chandler et al (US6093150). It would have been obvious in view of the latter that where a deformable Doppler ultrasound probe is used, plural transducers 6 are advantageous since additional information via Doppler imaging may be had, see Col. 6 lines 38-56 thereof.

Claims 14 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al in view of Chandler et al as applied to claim 14 above, and further in view of McLeod et al (US4142412). It would have been obvious in view of the latter Fig. 1 to orient a pair of doppler transducers 22A, 22B at approximately ninety degrees to each other and approximately 45 degrees to the longitudinal axis of the flow sensing probe because the Doppler angle has to be a non-perpendicular intercept to the adjacent flow being measured where this flow is known to be generally parallel to the probe's longitudinal axis.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al as applied to claim 1 above, and further in view of Boykin et al (US5360406). It would have been obvious in view of the latter, see col. 3 line 62 – col. 4 line 30 to anneal the stainless steel wire within 16 of Drost et al because annealing was known to soften steel wire to the bendability constraints desired in the former at col. 3 lines 8 – 10.(claim 24). When Drost et al is entertained regarding the cannula construct as per claim 2 discussion supra, the applicability of Boykin et al remains the same (Claim 25).

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Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al in view of Yock as applied to claim 33 above, and further in view of Gade, as the latter was applied against claim 4 supra.

Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al in view of Yock et al as applied to claim 40 above, and further in view of Salmon et al as the latter was applied against claims 10-12, supra.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al in view of Yock et al as applied to claim 33 above, and further in view of Chandler et al, as the latter was applied regarding claim 13 supra.

Claims 45 – 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drost et al in view of Yock et al and Chandler et al as applied to claim 44 above, and further in view of McLeod, as the latter was applied against claims 14-15 supra.

Allowable Subject Matter

Claims 16 –18, 20-23 are allowed.

Response to Amendment Remarks

Applicants' remarks on pages 8 – 9 of the amendment filed September 29, 2003 are a correct prosecution history and were troubling to the undersigned. The Meredith et al and Salmon et al patents were provided to Examiner Patel by myself in

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January 2003 with memorandum instructions on proper search, search terms and specific applicability of the references. The resultant Allowance Reasoning June 30, 2003 is therefore not comprehensible and should be ignored. The conclusion in Final Rejection paper No. 8 is likewise over-distilled so as to be incomprehensible. The applicability of this art for the record per those instructions from myself is:


' Navia et al (US6340356) in col. 7 lines 27 – 32 states that a Doppler flow sensor within the catheter's work cannula 18 may be delivered into the heart by threading over a malleable stylet thereby collectively forming a malleable Doppler probe.

Pless et al (US2002/0128639) teaches an introducer-stylet design for the ablation catheter which is malleable as opposed to pre-shaped, see para [0144], and for use in conjunction with a distal Doppler flow sensor to track circulatory level in terms of thermal carry-off to plan ablation energy, see para [0208]. '

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

2-24-2004


Francis J. Jaworski
Primary Examiner